

UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF OHIO  
EASTERN DIVISION

**IN RE: NATIONAL PRESCRIPTION  
OPIATE LITIGATION**

THIS DOCUMENT RELATES TO:

*The Montgomery County Board of County  
Commissioners et al. v. Cardinal Health, Inc.,  
et al.*, Case No. 1:18-op-46326-DAP (“Track  
Seven”)

MDL 2804

Case No. 1:17-md-2804

Judge Dan Aaron Polster

**PLAINTIFF’S MOTION FOR PARTIAL SUMMARY JUDGMENT ON DEFENDANTS’  
DUTIES UNDER THE CONTROLLED SUBSTANCES ACT**

On August 19, 2019, the Court ruled that the federal Controlled Substances Act (“CSA”), 21 U.S.C. §§ 801 *et seq.* and its implementing regulations, 21 C.F.R. 1301 *et seq.*, mandate that wholesale distributor registrants halt, and not ship, suspicious orders of prescription opioids unless and until they have determined that diversion is not likely. *In re Nat’l Prescription Opiate Litig.*, No. 1:17-MD-2804, 2019 WL 3917575, at \*9 (N.D. Ohio Aug. 19, 2019). The Court further observed that, with respect to the duty not to ship without due diligence, it was “hard-pressed to think of a more basic requirement.” *Id.* (The Court’s order also recognized the duties of distributors to provide effective controls against diversion and to design and implement systems to identify suspicious orders of controlled substances. Those duties were predicates for the Court’s ruling concerning the duty not to ship suspicious orders without due diligence.)

With respect to the duties of a dispenser, this Court ruled on August 6, 2020, that, like distributors, dispensers “have an affirmative obligation to protect not only against diversion via theft but also other forms of diversion more broadly.” *In re Nat’l Prescription Opiate Litig.*, 477

F. Supp. 3d 613, 625 (N.D. Ohio 2020). Construing DEA regulations, including 21 C.F.R. § 1301.71(a) (duty to provide effective controls against diversion) and 21 C.F.R. § 1306.04(a) (responsibility for ensuring that only valid prescriptions are dispensed), the Court further held that:

- “[B]oth pharmacists and pharmacies bear all the obligations imposed upon practitioners and dispensers.” *Id.* at 626.
- “[A] pharmacy owner, who is not him- or herself a licensed pharmacist, must employ a licensed pharmacist as a control against diversion, and *the pharmacy must conduct its business in a way that allows its pharmacist to properly dispense the pharmacy-licensee's controlled substances on its behalf.*” *Id.* at 628 (emphasis added).
- “[D]ispensers of controlled substances are obligated to check for and conclusively resolve red flags of possible diversion prior to dispensing those substances.” *Id.* at 629.
- Pharmacies “have an obligation under Ohio law to ‘allow[] pharmacists . to practice pharmacy in a safe and effective manner.’ . . . This can be “accomplished fully only when a pharmacy actually uses the data it is required to collect . . . to provide a tool otherwise unavailable to its pharmacists.” *Id.* at 631.
- Under the CSA, “a pharmacy is required to: (1) collect and maintain specific records and data regarding its dispensing activity; (2) employ a properly licensed pharmacist; and (3) properly dispense controlled substances and avoid diversion. Therefore, both the pharmacy and the pharmacist must cooperatively identify and resolve ‘red flags’ prior to dispensing controlled substances.” *Id.*
- Pharmacies “cannot collect data as required by the statute, employ a licensed pharmacist as required by the statute, identify red flags as required by Agency decisions, but then do nothing with their collected data and leave their pharmacist-employees with the sole responsibility to ensure only proper prescriptions are filled. Possessing, yet doing nothing with, information about possible diversion would actually *facilitate* diversion, and thus violate the CSA's fundamental mandate that ‘*All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances.*’ 21 C.F.R. § 1301.71(a)” *Id.* (emphasis by the Court).

These holdings are purely matters of law, not tied to the specific facts of the cases in which the orders were issued. They construe the CSA and set forth the framework for Defendants’ duties under the statute and its implementing regulations. They can, and should, be applied with equal force in this case track.

Rule 56 permits a party to move for summary judgment on a claim or defense or on a “part of [a] claim or defense.” Fed. R. Civ. P. 56(a). The rule thus “make[s] clear at the beginning that summary judgment may be requested not only as to an entire case but also as to a claim, defense, or part of a claim or defense.” Fed. R. Civ. P. 56, Advisory Committee Notes, subdivision (a) (2010). “Statutory interpretation is a matter of law appropriate for resolution on summary judgment.” *Thomas v. Metro. Life Ins. Co.*, 631 F.3d 1153, 1160 (10th Cir. 2011); *see also Walsh v. United States*, 31 F.3d 696, 698 (8th Cir. 1994) (where an unresolved issue is “primarily legal rather than factual, summary judgment is particularly appropriate.”); *Brown v. Smith*, 827 F.3d 609, 613 (7th Cir. 2016) (a “question of law” suitable for summary judgment “typically concerns the meaning of a statutory or constitutional provision, regulation, or common law doctrine”). Any factual distinctions between this case and the cases in which the Court issued its prior rulings are thus immaterial. *See, e.g., Chernin v. Welchans*, 641 F. Supp. 1349, 1358 (N.D. Ohio 1986) (factual disputes are not “material” where determination of the constitutionality of a law on its face is a legal, not factual, determination).

Moreover, in the context of multi-district litigation, it is especially important that this Court ensure consistent rulings on purely legal issues; that is one of the efficiencies for which the MDL process was designed. *See* 28 U.S.C. § 1407. It would be manifestly unjust for this Court to construe the same laws differently for different plaintiffs or different defendants.<sup>1</sup> Accordingly, this Court should grant Plaintiff’s motion for partial summary judgment with respect Defendants’

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<sup>1</sup> Indeed, Plaintiff contends that *all* of this Court’s MDL rulings on matters of law were meant, and ought, to be applicable in all case tracks, unless and until a defendant in a particular case demonstrates that there are different factual or other circumstances that warrant application of a different legal rule. *See Home Depot USA, Inc. v. Lafarge North Am., Inc.*, No. 22-1122, 2023 WL 1458892, at \*8–9 & n.6 (3d Cir. Feb. 2, 2023). Nonetheless, for the avoidance of doubt, Plaintiff has moved separately with respect to the construction of the CSA because that issue was previously addressed in connection with a motion for summary judgment.

legal duties under the CSA, applying its prior legal rulings consistently in this case.

### CONCLUSION

For the foregoing reasons, this Court should adopt its prior rulings, dated August 19, 2019 and August 6, 2020, about the scope of Defendants' duties under the CSA, including specifically that: (a) as distributors, Defendants were required to (i) provide effective controls against diversion of controlled substances; (ii) design and implement a system to detect suspicious orders of controlled substances; and (iii) halt shipment of suspicious orders unless and until they were able to determine through investigation that the order was not likely to be diverted; and (b) as dispensers, Defendants, and not merely their pharmacist employees, were required to (i) provide effective controls against diversion of controlled substances in both storage and dispensing, not merely to guard against theft; (ii) take appropriate measures to ensure that only valid prescriptions for controlled substances were dispensed from their stores; (iii) conduct their business in a way that allowed their pharmacists to properly dispense controlled substances on their behalf, including providing for the identification and resolution of "red flags" indicative of diversion; and (iv) make appropriate use of, and not ignore, data in their possession to assist in carrying out their obligation to dispense only valid prescriptions for controlled substances.

Dated: February 8, 2023

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I hereby certify that on February 8, 2023, I electronically filed the foregoing with the Clerk of Court by using the CM/ECF system and may be obtained by using the CM/ECF system. Copies will be served upon counsel of record by, and may be obtained through, the Court CM/ECF system.

/s/ Peter H. Weinberger

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